

# Guidance on Self-Testing and Over the Counter Testing for Individuals and Employers



The Washington Medical Test Site program has decided to align with the CMS Over the Counter (OTC) Home Testing and CLIA Applicability FAQ which was released on November 22, 2021, to hopefully simplify some of the confusion as to whether or not a Medical Test Site Waived (MTSW) license is required or not for businesses, schools, jails, shelters, etc.

## **Question: If my business does not want a Medical Test Site license but wants to be in compliance with regulations, what would the process for observing an employee performing a self-test look like?**

The employee must be self-directed in completing the over the counter test, in a circumstance where an employee has a disability and needs assistance please see the OTC CLIA Applicability FAQ guidance. The employer may do the following without the need for a license:

1. Hand the test kit (approved by FDA for over the counter use) to the employee along with the test manufacturer's instructions for use,
2. Ask the employee to carefully read and follow the package insert (following the instructions for use exactly is required),
3. Allow the employee to follow the instructions to collect the sample (swab themselves), and then run the test (encouraging the use of a timing device to ensure the test is read at the appropriate time is highly recommended),
4. Let the employee interpret or read the results (while being observed if observation is required).

After the employee has read or interprets the results the employer may then verify the results if they desire (ie. ask to view the kit or make an observation of the result).

**If a business, school, jail, shelter, etc. chooses to have a staff member performing the test and/or interpreting/reporting the test results, then they would need a MTSW license to perform the test even if the test is authorized by the FDA for home use.**

In Washington, to obtain a certificate of waiver, you need to [complete the MTS application](#) and not the federal 116 form used by other states. The first part of the packet is a checklist to help you fill out the application. You don't need to apply separately to the Centers for Medicare & Medicaid Services (CMS) for a CLIA number. Your MTS license will contain both your MTS license number and your CLIA number. Any questions regarding filling out the application can be directed to the Medical Test Site Program at [LQA@doh.wa.gov](mailto:LQA@doh.wa.gov)

### **Other information:**

All Medical Test Site license holders are required to report test results under the Notifiable Conditions Rule WAC 246-101-017.

Here is a great link to the CDC's resources on Self-Tests: [CDC Self-Testing Information](#).

To look up self-tests authorized by the FDA for home use, click on the following links: [Antigen-diagnostic-tests-sars-cov-2](#), [Molecular-diagnostic-tests-sars-cov-2](#), then scroll down to the table, enter "OTC" into the search bar. To note, an over the counter or self-test is also called a "home test" or an "at-home test." The [FDA OTC Reference](#) provides information on which self-tests are authorized for use. Tests in the table authorized as only "H, M, W" require Medical Test Site licensing unless the word "Home" or OTC is listed next to the test.